

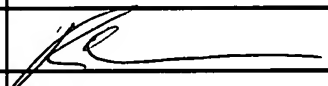
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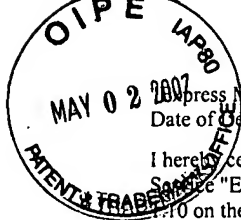
JPW 1654/15

PTO/SB/21 (09-04)

PTO TRANSMITTAL FORM (to be used for all correspondence after initial filing) PATENT & TRADEMARK OFFICE MAY 02 2007	Application Number	10/540,803
	Filing Date	June 23, 2005
	First Named Inventor	Green, et al.
	Art Unit	1654
	Examiner Name	Audet, Maury-A.
	Attorney Docket Number	022354-000310US

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment (13 pp.).	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request (1 p., submitted in duplicate).	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	Form PTO/SB/08A
<input checked="" type="checkbox"/> Supplemental Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s) _____	References (41)
	<input type="checkbox"/> Landscape Table on CD	Return postcard.
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<input type="checkbox"/> Reply to Missing Parts/ Incomplete Application		
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Townsend and Townsend and Crew LLP		
Signature			
Printed name	Randolph T. Apple		
Date	May 02, 2007	Reg. No.	36,429



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Date of Deposit May 2, 2007

PATENT
Attorney Docket No.: 022354-000310US

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Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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TOWNSEND and TOWNSEND and CREW LLP

By: 

Susan Aikins

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Daniel GREEN et al.

Application No.: 10/540,803

Filed: June 23, 2005

For: COMPOSITIONS AND METHODS
FOR THE PREVENTION AND
CONTROL OF INSULIN-INDUCED
HYPOGLYCEMIA

Confirmation No.: 7164

Examiner: Maury A. Audet

Art Unit: 1654

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT UNDER
37 CFR §1.97 and §1.98

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references [in compliance with the requirements of 37 CFR §1.98(a)(2)] are enclosed.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

05/07/2007 SSITHIB1 00000022 10540803

01.FC:1806 180.00 DA

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This IDS is being filed before the mailing date of the final Office Action or Notice of Allowance.

Please charge the IDS fee of \$180 to Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Randolph Ted Apple
Reg. No. 36,429

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: 650-326-2422
RTA:sra



Substitute for form 1449A&B/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Application Number	10/540,803	
			Filing Date	June 23, 2005	
			First Named Inventor	Green, Daniel T.	
			Art Unit	1654	
			Examiner Name	Maury A. Audet	
Sheet	1	of	4	Attorney Docket Number	022354-000310US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code ² (if known)			
	1	3,897,551	07-29-1975	Bromer	
	2	4,492,684	01-08-1985	Goosen et al.	
	3	4,498,843	02-12-1985	Schneider et al.	
	4	4,826,763	05-02-1989	Norris et al.	
	5	4,839,174	06-13-1998	Baker et al.	
	6	4,943,435	07-24-1990	Baker et al.	
	7	5,234,903	08-10-1993	Nho et al.	
	8	5,359,030	10-25-1994	Ekwuribe	
	9	5,445,832	08-29-1995	Orsolini et al.	
	10	5,637,568	06-10-1997	Orsolini et al.	
	11	5,643,604	07-01-1997	Angeles Uribe et al.	
	12	5,643,607	07-01-1997	Okada et al.	
	13	5,707,641	01-13-1998	Gertner et al.	
	14	5,849,322	12-15-1998	Ebert et al.	
	15	5,869,602	02-09-1999	Jonassen et al.	
	16	6,103,233	08-15-2000	Pouletty et al.	
	17	6,107,489	08-22-2000	Krantz et al.	
	18	6,114,304	09-05-2000	Kolterman et al.	
	19	6,191,105	02-20-2001	Ekwuribe et al.	
	20	6,197,333	03-06-2001	Onyuksel et al.	
	21	6,217,893	04-17-2001	Pellet et al.	
	22	6,239,107	05-29-2001	Gozes et al.	
	23	6,277,863	08-21-2001	Krantz et al.	
	24	6,284,727	09-04-2001	Kim et al.	
	25	6,319,510	11-20-2001	Yates	
	26	6,329,336	12-11-2001	Bridon et al.	
	27	6,348,214	02-19-2002	Onyuksel et al.	
	28	6,500,918	12-31-2002	Ezrin et al.	
	29	6,559,122	05-06-2003	Oeswein et al.	
	30	6,573,238	06-03-2003	Shirley et al.	
	31	6,589,548	07-08-2003	Oh et al.	
	32	6,593,295	07-15-2003	Bridon et al.	
	33	6,703,365	03-04-2004	Galloway et al.	

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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.



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				Examiner Name	Maurly A. Audet
Sheet	2	of	4	Attorney Docket Number	022354-000310US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	34	2001/0016643	08-23-2001	Jonassen et al.	
	35	2001/0033858	10-25-2001	Zhang	
	36	2002/0114829	08-22-2002	Onyuksei et al.	
	37	2002/01155920	08-22-2002	New et al.	
	38	2003/0108568	01-12-2003	Bridon et al.	
	39	2004/0110817A1	06-2004	Bernard Hulin	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document ³			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴	Kind Code ⁴ de ⁵ (if known) ⁴				
	40	EP	0 300 552		01-25-1989	Cordis Europa N.V.		<input type="checkbox"/>
	41	EP	0442724		08-21-1991	Kirin Amgen Inc.		<input type="checkbox"/>
	42	EP	0684044		11-29-1995	Johan F. Jensen, et al.		<input type="checkbox"/>
	43	EP	0816381		01-07-1998	Toshikazu Nakamura, et al.		<input type="checkbox"/>
	44	EP	1264837		12-11-2002	Nobex Corp.		<input type="checkbox"/>
	45	WO	8809341		12-01-1988	Robert B. Merrifield		<input type="checkbox"/>
	46	WO	9703688		02-06-1997	Miriam Kidron et al.		<input type="checkbox"/>
	47	WO	9724440		07-10-1997	Genentech Inc.		<input type="checkbox"/>
	48	WO	9808871		03-05-1998	Novo Nordisk A/S		<input type="checkbox"/>
	49	WO	9831383		07-23-1998	Phoenix Pharmacologics Inc.		<input type="checkbox"/>
	50	WO	9943708		09-02-1999	Novo Nordisk A/S		<input type="checkbox"/>
	51	WO	0182874		11-08-2001	Aeropharm Technology Inc.		<input type="checkbox"/>
	52	WO	0182981		11-08-2001	Aeropharm Technology Inc.		<input type="checkbox"/>
	53	WO	0222154		03-21-2002	Praecis Pharmaceuticals Inc.		<input type="checkbox"/>
	54	WO	0232957		04-25-2002	Chugai Seiyaku Kabushiki Kaisha		<input type="checkbox"/>
	55	WO	0246227		06-13-2002	Eli Lilly and Company		<input type="checkbox"/>
	56	WO	04060387	A1	07-22-2004	Diobex Inc.		<input type="checkbox"/>
								<input type="checkbox"/>

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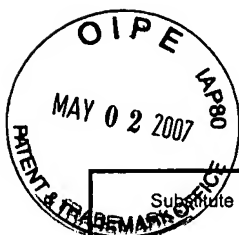


Substitute for form 1449A&B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
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				Art Unit	1654
				Examiner Name	Maury A. Audet
Sheet	3	of	4	Attorney Docket Number	022354-000310US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	57	AMERICAN DIABETES ASSOCIATION, "Defining and Reporting Hypoglycemia in Diabetes," Diabetes Care, 28:1245-1249 (2005)	<input type="checkbox"/>	
	58	BEAVEN et al., European J. Biochem., 11:37-42 (1969)	<input type="checkbox"/>	
	59	CHIOU et al., "Adjustment of Blood Sugar Levels with Insulin and Glucagons Eyedrops in Normal and Diabetic Rabbits," J Ocul Pharmacol., 6(3):233-41, Fall 1990	<input type="checkbox"/>	
	60	CHIOU et al., "Treatment of Hypoglycemia with Glucagon Eye Drops," J Ocul Pharmacol., 4(2):179-86, Summer 1988	<input type="checkbox"/>	
	61	CHUANG et al., "Increase of Blood Glucose Concentrations in Diabetic Patients with Glucagon Eyedrops," Zhongguo Yao Li Xue Bao, 13(3):193-7, May 1992	<input type="checkbox"/>	
	62	FABRIS et al., Nasal Administration of Glucagon in the Treatment of Neonatal Hypoglycemia," Minevraa Pediatr. 36(2):525-8, May 31, 1984	<input type="checkbox"/>	
	63	GAMBA et al., Minevra Med. 1977 Nov 3; 68(53):3613-26	<input type="checkbox"/>	
	64	HOULBERT et al., "Continuous Subcutaneous Infusion of Glucagon by Portable Pump in Non Beta Cell Tumor Hypoglycemia," Diabete & Metab. 11(2):125-7, April 1985	<input type="checkbox"/>	
	65	JOSEPH et al., "Oral Delivery of Glucagon-like Peptide-1 in a Modified Polymer Preparation Normalizes Basal Glycaemia in Diabetic db/db Mice," Diabetologia, 43(10):1319-28, Oct 2000	<input type="checkbox"/>	
	66	KAINDL et al., Inn Med. 1972 Dec 15: 27(24):1097-8	<input type="checkbox"/>	
	67	KAINDL et al., Verh Dtsch Ges Inn Med. 1972 Apr; 78:1099-101		
	68	LUND et al., Proc. Natl. Acad. Sci. USA 79:345-349 (1982)		
Examiner Signature				Date Considered

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				Examiner Name	Maury A. Audet
Sheet	4	of	4	Attorney Docket Number	022354-000310US

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	69	MIRALLES et al; "Experience With Intravenous Glucagon Infusions as a Treatment for Resistant Neonatal Hypoglycemia," Arch. Pediatr Adolesc Med., 156(1):999-1004, Oct 2002		
	70	MUHLHAUSER et al., "Experience with Intravenous Glucaagon Infusions as a Treatment for Resistant Neonatal Intramuscula, Subcutaneous, and Intravenous Administration," Diabetes Care, 8(1):39-41 Jan-Feb 1985		
	71	PAOLISSO et al., "Pulsatile Rather Than Continuous Glucagon Infusion Leads To Greater Metabolic Derangements In Insulin-Dependent Diabetic Subjects," Diabete Metabl., 1990, Jan-Feb; 16(1):42-7 (abstract)		
	72	PATZELT et al., "Identification and Processing of Proglucagon in Pancreatic Islets." Nature, 282:260-266 (1979)		
	73	PILLION et al., "Glucagon Administration to the Rat via Eye Drops," J Ocul Pharmacol., 8(4):349-58, Winter 1992		
	74	PILLION et al., "Systemic Absorption of Insulin and Glucagon Applied Topically to the Eyes of Rats and Diabetic Dog," J Ocul Pharmacol Ther., 11(3):238-95, Fall 1995		
	75	PONTIROLI et al., "Metabolic Effects of Intranasally Administered Glucagon: Comparison with Intramuscular and Intravenous Injection," Acta Diabetol Lat.22(2):103-10, April-June 1985		
	76	ROSENFALCK et al., "Nasal Glucagon in the Treatment of Hypoglycaemia in type 1 (Insulin-Dependent) Diabetic Patients," Diabetes Res Clin Pract. 17(1):43-50 July 1992		
	77	STENNINGER et al., "Intranasal Glucagon Treatment Relieves Hypoglycaemia in Children with Type 1 (Insulin-Dependent) Diabetes Mellitus," Diabetologia. 36(10):931-5, Oct 1993		
	78	STURM et al., Structure-Function Studies on Positions 17, 18, and 21 Replacement Analogues of Glucagon: The Importance of Charged Residues and Salt Bridges on Glucagon Biological Activity," J. Med. Chem. 41:2693-2700 (1998)		
	79	WEBB et al., "Glucagon Replacement via Micro-Osmotic Pump Corrects Hypoglycemia and alpha-cell Hyperplasia in Prohome Convertase 2 Knockout Mice," Diabetes 51(2):398-405, Feb 2002		

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